January 7, 2014

Independent Data Monitoring Committee Recommends Early Stopping of Phase 3 Study of Ibrutinib in Relapsed/Refractory CLL/SLL Patients Based on a Planned Interim Analysis

RARITAN, NJ, January 7, 2014 -- Janssen Research & Development, LLC today announced the early stopping of PCYC-1112-CA, the Phase 3 study of IMBRUVICA™ (ibrutinib) in the treatment of chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL), based on the recommendation of an Independent Data Monitoring Committee (IDMC), which concluded that the study showed a significant difference in progression-free survival (PFS) as compared to the control, the primary endpoint of the study.

Study PCYC-1112-CA (RESONATE) is an international, randomized, open-label Phase 3 clinical study including 391 patients with relapsed or refractory CLL/SLL with measurable nodal disease and who were not eligible for treatment with purine analog-based therapy, who had received at least one prior therapy. Patients were randomized to receive 420 mg of ibrutinib orally once daily or intravenous doses of ofatumumab, an approved treatment for relapsed/refractory CLL, over the course of 24 weeks. Both treatments were administered until disease progression or unacceptable toxicity.

The primary endpoint of the study is PFS; overall survival (OS) is a key secondary endpoint; others included overall response rate and safety.

"We're delighted with this outcome, and look forward to sharing these results with the scientific community and Health Authorities," said Peter F. Lebowitz, MD, PhD, Oncology Therapeutic Area Head, Janssen Research & Development, LLC. "This Phase 3 randomized study provides a useful head-to-head comparison of single agent ibrutinib versus ofatumumab, and builds upon the early evidence of clinical benefit observed in the ibrutinib Phase 2 program."

The IDMC unanimously recommended stopping the study early based on a planned interim analysis, in which statistically significant differences in PFS (as assessed by an independent review committee) and OS were observed. The IDMC agreed that these results suggest evidence of clinical benefit as well as a tolerable safety profile in patients receiving ibrutinib as compared to intravenous doses of ofatumumab. The IDMC also recommended that the sponsor provide access to ibrutinib to patients in the ofatumumab arm.

These results will be presented at an upcoming medical meeting and also will be submitted for publication in a peer-reviewed journal.

About Ibrutinib (IMBRUVICA™)
Ibrutinib was approved in November 2013 in the U.S. under the tradename IMBRUVICA™, as a single agent for the treatment o patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is based on overall response rate. An improvement in survival or disease-related symptoms has not been established.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
Hemorrhage - Five percent (5%) of patients with MCL had Grade 3 or higher bleeding events (subdural hematoma, gastrointestinal bleeding, and hematuria). Bleeding events including bruising of any grade occurred in 48% of patients with MCL treated with 560 mg daily. The mechanism for the bleeding events is not well understood. Consider the benefit-risk of ibrutinib in patients requiring antiplatelet or anticoagulant therapies and the benefit-risk of withholding ibrutinib for at least 3 to 7 days pre and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections - Fatal and non-fatal infections have occurred. At least 25% of patients with MCL had infections ≥ Grade 3, according to NCI Common Terminology Criteria for Adverse Events (CTCAE). Monitor patients for fever and infections and evaluate promptly.

Myelosuppression - Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients. These included neutropenia (29%), thrombocytopenia (17%) and anemia (9%). Monitor complete blood counts monthly.

Renal Toxicity - Fatal and serious cases of renal failure have occurred. Treatment-emergent increases in creatinine levels up to 1.5 times the upper limit of normal occurred in 67% of patients and from 1.5 to 3 times the upper limit of normal in 9% of patients. Periodically monitor creatinine levels. Maintain hydration.

Second Primary Malignancies - Other malignancies (5%) have occurred in patients with MCL who have been treated with IMBRUVICA, including skin cancers (4%), and other carcinomas (1%).

Embryo-Fetal Toxicity - Based on findings in animals, IMBRUVICA can cause fetal harm when administered to a pregnant woman. Advise women to avoid becoming pregnant while taking IMBRUVICA. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse Reactions - The most commonly occurring adverse reactions (≥ 20%) in the clinical trial were thrombocytopenia*, diarrhea (51%), neutropenia*, anemia*, fatigue (41%), musculoskeletal pain (37%), peripheral edema (35%), upper respiratory tract infection (34%), nausea (31%), bruising (30%), dyspnea (27%), constipation (25%), rash (25%), abdominal pain (24%), vomiting (23%) and decreased appetite (21%).

* Treatment-emergent decreases (all grades) of platelets (57%), neutrophils (47%) and hemoglobin (41%) were based on laboratory measurements and adverse reactions.

The most common Grade 3 or 4 non-hematological adverse reactions (? 5%) were: pneumonia (7%), abdominal pain (5%), atrial fibrillation, diarrhea (5%), fatigue (5%), and skin infections (5%). Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients.

Ten patients (9%) discontinued treatment due to adverse reactions in the trial (N=111).

The most frequent adverse reaction leading to treatment discontinuation was subdural hematoma (1.8%). Adverse reactions leading to dose reduction occurred in 14% of patients.

Drug Interactions:
CYP3A Inhibitors - Avoid concomitant administration with strong or moderate inhibitors of CYP3A. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA dose.

CYP3A Inducers - Avoid co-administration with strong CYP3A inducers.

Special Populations - - Avoid use in patients with baseline hepatic impairment.

For the full prescribing information, visit http://www.imbruvica.com/downloads/Prescribing_Information.pdf

Ibrutinib has been submitted to the European Medicines Agency (EMA) for the treatment of adult patients with relapsed or CLL/SLL or adult patients with relapsed or refractory MCL. Use of ibrutinib in markets and for indications in which it has not been approved is investigational.

Ibrutinib is being jointly developed and commercialized by Janssen and Pharmacyclics, Inc. Pharmacyclics sponsored the study.

For more information, visit www.IMBRUVICA.com.

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
Chronic Lymphocytic Leukemia (CLL) is a slow-growing cancer of the white blood cells (lymphocytes), most commonly B cells. CLL is the most common adult leukemia. Small Lymphocytic Lymphoma (SLL) is a slow-growing lymphoma in which too many immature white blood cells cause lymph nodes to become larger than normal.

About Janssen Research & Development, LLC
At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development is part of the Janssen Pharmaceutical Companies. Please visit www.janssenrnd.com for more information.

Janssen in Oncology
In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statements as a result of new information or future events or developments.)

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